Appendix B

Workstations Manual for TOSCA Workstation TMS-2N, TOSCA Workstation TMS-3, and WASCA Workstation

Asclepion
Meditec

Workstations

TOSCA Workstation TMS-2N | TOSCA Workstation TMS-3 | WASCA Workstation

USER MANUAL

Document No. 310599001
Version 2.1
Closing date 06/2002

Ablation Generator to V 3.3.5
System-related software:
OPASS to V 3.1
TMS-2N to V 2.4.2 J
TMS-3 to V 2.2.3
WASCA V 1.26.3

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Imprint

Dear customer,

you have decided to use a topographic system from Asclepion-Meditec AG. Congratulations! Now you are the owner of such an advanced system for the topographic acquisition and evaluation of the aberration of the human eye.

This Workstations enables you to generate data records for ablation specific to each individual patient with high precision and transfer the data to the Excimerlaser MEL 70 *G-Scan* for carrying out the treatment.

If you have any questions or would like to make any comments, please contact us.

Document

Workstations · User Manual I Document No. 310599001 I Version 2.1 I Closing date 06/2002

This User Manual contains a summary of the description of individual units of the workstations offered by Asclepion-Meditec AG. The summary is limited to the description of units, general safety information, transport and installation, start-up, operation of the ablation generator software, troubleshooting and remedial action, cleaning and maintenance, and other important points. Expressly excepted from this Manual are descriptions of specific medical states or any additional functions as well as the detailed description of using the data-collecting topography systems and specific software of these systems. We refer you to the OEM documentation supplied with these instructions.

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Table of contents

1 General information

1.1 Identification data

Machine data

Model designation: _____

Serial number: _____

Order number: _____

Year of construction: _____

Software data

License ID: _____

Serial number: _____

Operation system: _____

Distributor

Firm/name: _____

Address: _____

Phone no.: _____

1.2 Direction for User Manual

Purpose of this document

This User Manual contains a summary of the description of individual units of the workstations offered by Asclepion-Meditec AG. The summary is limited to the description of units, general safety information, transport and installation, start-up, operation of the ablation generator software, troubleshooting and remedial action, cleaning and maintenance, and other important points. Expressly excepted from this Manual are descriptions of specific medical states or any additional functions as well as the detailed description of using the data-collecting topography systems and specific software of these systems. We refer you to the OEM documentation supplied with these instructions.

Availability of this document

Always keep the User Manual and the other documents available to the operator.
The User Manual should always be readily available for consultation.

Complete documentation

Part of the scope of the Workstation, in addition to this User Manual, are all OEM product descriptions of system components which Asclepion-Meditec AG purchases from other suppliers. Related documents are:

- Medical Device Logbook · Asclepion-Meditec AG
- **TOSCA TMS-2N:** – Operator Manual · Tomey Corporation
- **TOSCA TMS-3:** – Operator Manual · Fortune Technologies
- **WASCA Wavefront Analyzer:** – User Manual · Asclepion-Meditec AG
  – WASCA Booklet · Asclepion-Meditec AG
  – Short Operating Instruction · Asclepion-Meditec AG

Symbols

The following symbols are used throughout the User Manual to indicate hazards and special advice.

Danger!

This symbol indicates a hazardous situation which, if not avoided, will result in death or serious injury.

Caution!

This symbol indicates a hazardous situation which, if not avoided, will result in damage to the equipment, material or the environment. It is also used to indicate potentially hazardous handling in diagnostic applications.

Note!

This symbol indicates information and provides interesting advice for a better understanding of the equipment or its diagnostic capabilities, respectively.

2 Description of units

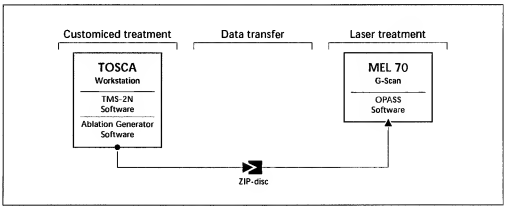
2.1 TOSCA Workstation TMS-2N

2.1.1 Technical conception

The TOSCA Workstation TMS-2N is a diagnostic instrument for collecting information about corneal shape and refractive characteristics. Unlike a conventional keratoscope, it uses computer technology to create color maps for easier and more accurate analysis of corneal shape.

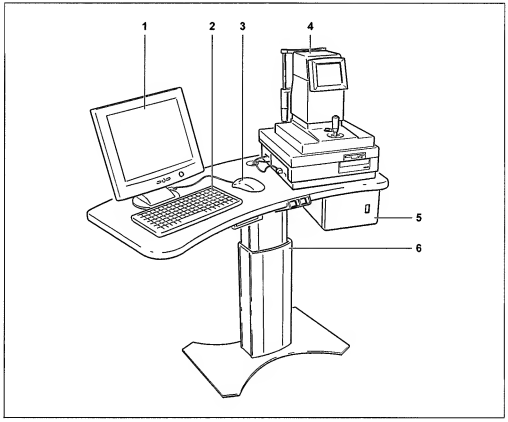
The TMS-2N data record is sent to the Ablation Generator software. The user can verify the data string with the Ablation Generator software, reference it to other diagnostic data, edit data and finally generate a data record for an Excimerlaser MEL 70 *G-Scan*.

The data record is transferred via ZIP-disc to the MEL 70 *G-Scan*. Now the OPASS software processes the data on the Excimerlaser MEL 70 *G-Scan*.



2.1.2 Construction

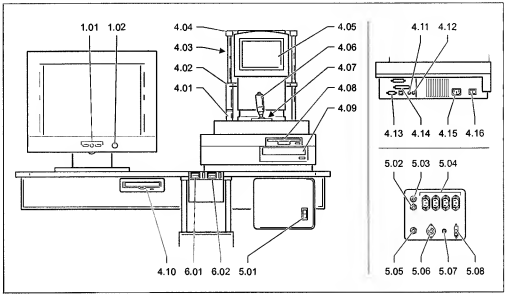
System overview



Legend:

1 TFT flat screen with power supply unit and connecting cable to the computer
2 Keyboard
3 Mouse
4 TMS-2N Topographic Modeling System with Computer and power supply cable
5 Overall system isolation transformer (main power supply)
6 Overall system power table

Controls and connections



Legend:

1.01	Monitor controls
1.02	Monitor main switch ON/OFF
4.01	Chin rest height adjustment knob
4.02	Chin rest
4.03	Cone (on the back side)
4.04	Forehead rest
4.05	LCD monitor
4.06	Joystick with button
4.07	VKS platform lock (behind the joystick)
4.08	3½" Floppy disc drive
4.09	CD-ROM drive
4.10	ZIP drive
4.11	Mouse connection
4.12	Keyboard connection
4.13	Monitor connection
4.14	Printer connection
4.15	Power connection
4.16	Power switch (TMS-2N) ON/OFF
5.01	Main switch ON/OFF
5.02	Power table line feed through
5.03	Mains voltage feed through (inlet)
5.04	230 V AC outlets
5.05	TMS-2N power supply cable
5.06	Voltage selector with integrated primary fuse
5.07	Secondary primary fuse
5.08	Secondary side overload protection
6.01	Power table ON/OFF pushbutton
6.02	Power table height control

2.1.3 Function

The TOSCA Workstation TMS-2N uses a Light Cone™ solid-state videokeratoscope that projects illuminated concentric rings onto the patient's cornea at approximately 180 micron intervals. These rings are reflected from the cornea. An image of the corneal surface and reflected rings is captured and stored in digital form. The image is then analyzed by a program that identifies the location of 256 circumferential points on each ring. The dioptric power, radius of curvature and height of the cornea at each point is determined. This information may subsequently be displayed using a variety of map representations and scale.

2.1.4 Technical data

TOSCA Workstation TMS-2N (overall system)

Dimensions W x D x H:	1.2 m x 0.6 m x 1.5 m
Weight:	approx. 70 kg
Power supply:	115–230 V AC, single-phase, 6.3 A, 50–60 Hz
Power consumption:	approx. 100 W
Class of electric protection:	Class 1, type B, continuous service
License/test:	CE label
Ambient conditions:	10–40°C, 30–75 % RH

TMS-2N Topographic Modeling System

For technical data and further specification details, please refer to the operator manual of the supplier, Tomey Corporation.

TFT flat screen

For technical data and further specification details, please refer to the supplier's documentation in the supply.

2.2 TOSCA Workstation TMS-3

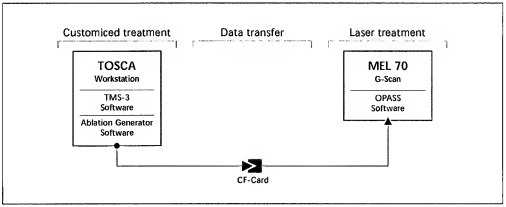
2.2.1 Technical conception

The TOSCA Workstation TMS-3 is an advanced system for the acquisition and diagnosis of the superficial conditions of the cornea. The system supplies data for the planning, design and later performance of refractive intervention with the Excimerlaser MEL 70 *G-Scan*.

With a CCD camera, the TMS-3 AutoTopographer scans the patient's eye and generates the elevation contour of the cornea. The required data record is generated by the TMS-3 software supplied with the TMS-3 AutoTopographer.

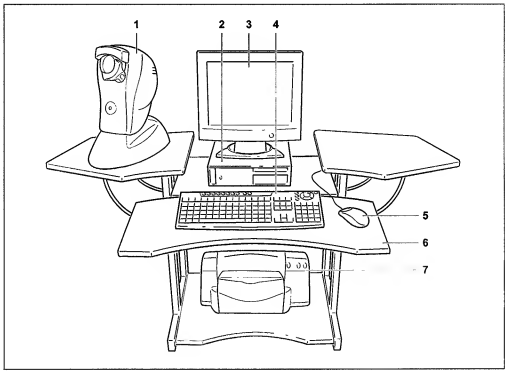
The TMS-3 data record is sent to the Ablation Generator software. The user can verify the data string with the Ablation Generator software, reference it to other diagnostic data, edit data and finally generate a data record for an Excimerlaser MEL 70 *G-Scan*.

The data record is transferred via CompactFlash-Card to the MEL 70 *G-Scan*. Now the OPASS software processes the data on the Excimerlaser MEL 70 *G-Scan*.



2.2.2 Construction

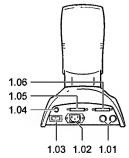
System overview

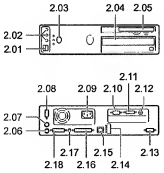


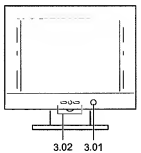
Legend:

1 TMS-3 AutoTopographer with power supply cable and parallel cable to the computer
2 Computer with power supply cable
3 TFT flat screen with power supply unit and connecting cable to the computer
4 Keyboard
5 Mouse
6 Computer table
7 Printer

Controls and connections







TMS-3 AutoTopographer

1.01 Main fuse
1.02 Power connection
1.03 Main switch ON/OFF
1.04 Video OUT
1.05 Parallel IN
1.06 Parallel OUT

Computer

2.01 USB connection
2.02 Audio adapter
2.03 Main switch ON/OFF
2.04 CD-ROM drive
2.05 3½" Floppy disc drive
2.06 Keyboard connection
2.07 Mouse connection
2.08 Serial port
2.09 Power connection
2.10 VGA port
2.11 Panel link (not used)
2.12 Video IN
2.13 VGA port for TFT flatscreen
2.14 Diagnostic LED
2.15 Network Hub
2.16 Printer connection
2.17 Speaker connection
2.18 Game connection

TFT flat screen

3.01 Monitor main switch ON/OFF
3.02 Monitor controls

2.2.3 Function

The CCD camera of the TMS-3 AutoTopographer produces the elevation contour of the examined patient's eye.

The image captured by the camera is displayed on the video monitor in real-time mode.

The connected computer processes all data and allows user intervention with the software.

The TMS-3 software interprets the results of the camera and generates the data records.

These data records are sent to the TOSCA software for processing. The user can verify the data contents, reference data to other diagnostic data and edit data.

The revised data records can then be transferred to an Excimerlaser MEL 70 *G-Scan* for further processing by the OPASS software.

2.2.4 Technical data

TOSCA Workstation TMS-3 (overall system)

Dimensions W x D x H:	1.5 m x 1.0 m x 1.4 m
Weight:	40 kg
Power supply:	220–230 V, single-phase, 6.3 A, 50–60 Hz
Power consumption:	150 W
Class of electric protection:	1, type B, continuous service
License/test:	CE label
Ambient conditions:	15–35°C, 20–50 % RH

TMS-3 AutoTopographer

For technical data and further specification details, please refer to the operator manual of the supplier, Fortune Technologies.

Computer, TFT flat screen and Printer

For technical data and further specification details, please refer to the supplier's documentation in the supply.

2.3 WASCA Workstation

2.3.1 Technical conception

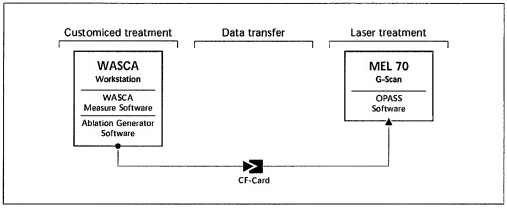
The WASCA Workstation is an advanced system for the acquisition and diagnosis of the visual performance of the eye. The system supplies data for the planning, design and later performance of refractive intervention with the Excimerlaser MEL 70 *G-Scan*. The Analyzer performs a complete analysis of the refractive path of light inside the eye based on the advanced wavefront analysis technology.

It ushers in a new era of precision in ophthalmic measurements. Directing a point of light at the retina, the WASCA Wavefront Analyzer resolves the reflected wavefront to provide nearly instantaneous, high precision measurements of primary and higher order aberrations of the eye. Application of the WASCA Wavefront Analyzer will allow you to make accurate measurements (to within 0.1 D for sphere and cylinder) and can help you specifically quantify the corrections needed for various eye abnormalities.

The WASCA Wavefront Analyzer is an instrument that measures the wavefront of light using a technique called the Shack-Hartmann wavefront sensor. This sensor consists of an array of tiny lenses (called lenslets) mounted in front of a video camera (or CCD).

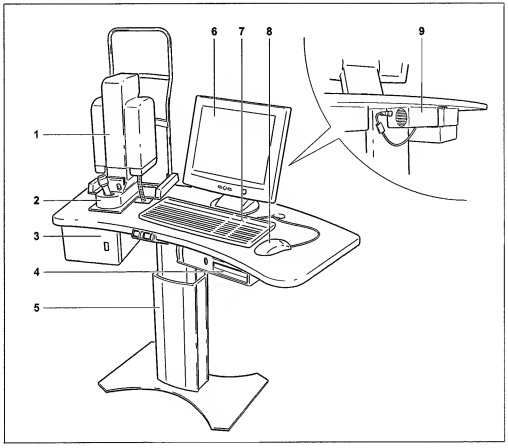
The WASCA Measure Software data record is send to the Ablation Generator Software. The user can verify the data string with the Ablation Generator Software, reference it to other diagnostic data, edit data and finally generate a data record for an Excimerlaser MEL 70 *G-Scan*.

The data record is transferred via CompactFlash-Card to the MEL 70 *G-Scan*. Now the OPASS software processes the data on the Excimerlaser MEL 70 *G-Scan*.



2.3.2 Construction

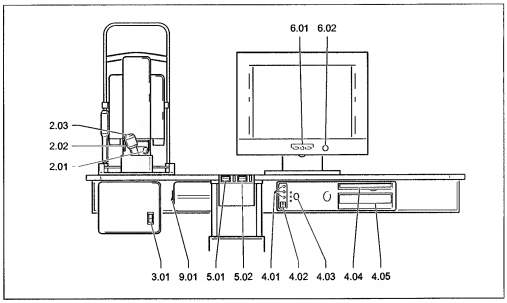
System overview



Legend:

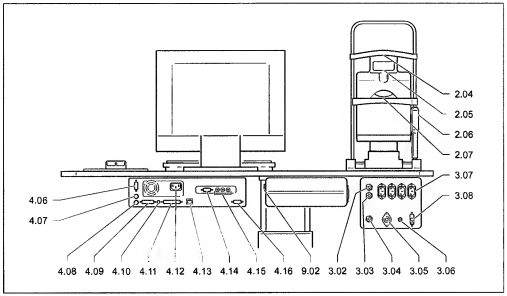
1 WASCA Wavefront Analyzer main unit with power supply cable, three video cables and a serial cable
2 xyz stage for precision alignment of the measuring head comprising head and chin rest
3 Overall system isolation transformer (main power supply)
4 Computer with power supply cable
5 Overall system power table
6 TFT flat screen with connecting cable to the computer
7 Keyboard
8 Mouse
9 Aberrometer power supply underneath the table hidden by the shied

Controls and connections



Legend:

2.01 Fixation target brightness control
2.02 Stage lock
2.03 Joystick for alignment of the instrument's optical entrance in front of the eye
3.01 Isolating transformer ON/OFF switch
4.01 Audio adapter
4.02 USB port
4.03 Computer ON/OFF switch
4.04 3½" Floppy disc drive
4.05 CD-ROM drive
5.01 Power table ON/OFF push button
5.02 Power table height control
6.01 Monitor controls
6.02 Monitor ON/OFF switch
9.01 Aberrometer power supply ON/OFF switch



Legend:

2.04	Head rest
2.05	Examination window, i.e. optical entrance
2.06	Chin rest height control
2.07	Chin rest
3.02	Mains voltage feed through (inlet)
3.03	Power table line feed through
3.04	Aberrometer power supply cable feed through
3.05	Voltage selector with integrated primary fuse
3.06	Secondary primary fuse
3.07	230 V AC outlets
3.08	Secondary side overload protection
4.06	WASCA measure head umbilical Sub-D connection to serial port of PC
4.07	Computer mouse connection to MSI computer
4.08	Keyboard connection to MSI computer
4.09	Game port (unused)
4.10	Speaker port (unused)
4.11	Printer port (unused)
4.12	Computer power supply line plug
4.13	Network hub (unused)
4.14	VGA port (unused)
4.15	Retina/wavefront/Iris camera video connector
4.16	VGA port for TFT flatscreen
9.02	Socket for aberrometer power supply

2.3.3 Function

The WASCA Wavefront Analyzer system is designed in such a way to facilitate your examination of eye aberrations. The alignment of the patient's eye directly in front of the examination window is performed with the help of an iris camera picture that is displayed in the screen. Subsequently, the measurement with the aberrometer can be carried out. Following the creation of the retinal spot (measuring light, i.e. Laser Class 1), a bundle of light travels out of the eye. This bundle passes through the optical train of the device and is directly imaged onto the Shack-Hartmann sensor. The sensor consists of a lenslet array that is connected to a CCD camera. It is sensitive to alteration in the wavefront slope. The CCD image is sent to a computer which enables data acquisition and data storage. The PC is equipped with a user friendly software and a flat panel TFT monitor that altogether gives you access to a comprehensive data inspection and evaluation on the fly. This allows you to select the best data sets or repeat measurement immediately and allows for several possibilities of intervention through the software control. The data are displayed as colored wavefront maps of aberrations, i.e. a "height map" across the eye simply given in µm. 3D elevation contour phase maps of the examined patient's eye are available for your convenience as well. We emphasize that you also have constant access to the raw data fed from the Shack-Hartmann sensor to convince yourself of the quality of the measured sensor pixels in case of doubt.

The data will be recorded into an easy-to-use data base arranged by patient name and examination date/time for convenient use. It should be noted that only the analyzed data (ZERNIKE terms) are stored in the database. These records can be retrieved, e.g. for further inspection or comparison. For improved data storage, i.e. the Shack-Hartmann wavefront sensor data, the so-called raw data can be saved as well. This allows for a complete re-analysis with new or different analysis parameters after each data retrieval.

The entire measurement will take only a few seconds and is mainly defined by the mechanical movement of the slider (a mechanically translation stage inside the aberrometer) that provides the correct setting of the sphere value. The method uses several light flashes from an SLD (Super Luminescence Diode) to cover the optical characteristics of the eye. The measurement light is in the near infrared region of the spectrum where the eye is nearly insensitive and is hence not irritated by the flashes. The duration of SLD light flashes is about 250 msec at less than 50 µWatt. That means that under all circumstances a safe eye illumination well below the MPE (Maximum Permissible Exposure) is ensured for proper use of the device. Data acquisition with the Shack-Hartmann sensor takes only 13 msec and safeguards minimal eye movements during the data acquisition.

2.3.4 Technical data

WASCA Wavefront Analyzer (overall system)

Dimensions W × D × H:	1.16 m × 0.53 m × 1.46 m
Weight:	approx. 75 kg
Power supply:	Input Rating: (100, 120, 208, 220, 230, 240) V single-phase, 6.3 A, 50–60 Hz
	Output Rating: 230 V single-phase, 3 A, 50–60 Hz
Power consumption:	max. 300 W; depending on power table function
Class of electric protection:	1, type B, continuous service
License/test:	CE label

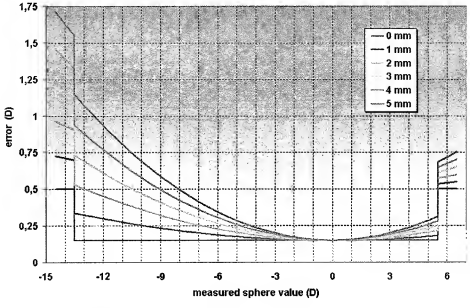
WASCA Wavefront Analyzer: Demonstrated specifications

Dioptric Range	Sphere: –15 D to +7 D, includes 5 D Cylinder
Spatial Resolution:	210 µm
Measurements Available:	Sphere, Cylinder, Cylinder-Axis, Seidel Aberration, ZERNIKE Polynomial Coefficients, Pupil size, RMS Wave front, Wave front Peak-to-Valley
Accuracy (S, C, A):	±0.15 D in the range: sphere –14 D to +6 D, including 3 D Cylinder
	±0.5 D in the range: sphere –15 D to +7 D, including 5 D Cylinder in each case for exactly aligned working distance and 6 mm pupil
Repeatability (S, C, A):	0.1 D (STD)
Total refraction speed:	about 5 seconds, including range detection and setting
Working distance:	50 mm (distance eye-exit optical train (not seen))
Fogging:	1.5 D, Fixed
Focal sensitivity:	depends on wanted accuracy (see below)
Alignment type:	Video alignment integrated with computer display
Patient interface:	Fixed headrest with adjustable chin height, XYZ stage alignment with adjustable WASCA elevation.
Clinician interface:	Computer video display, keyboard, mouse, XYZ stage adjustment via joystick, integrated refract and capture button on joystick.
Output devices:	Computer display, printer optional. Patient data are automatically stored on hard drive.

Confidence intervals

The distance from the measure head to the cornea of the examined eye has an influence on the measurement results. The proper distance has to be set up during the alignment procedure. The correct distance is achieved when the video image of the 6 adjustment LED's (reflected at the surface of the cornea) is in focus. Because the sharpness of the video image is a subjective factor there is a uncertainty in the correct distance witch depends on the skill of the user and the ambient conditions. The WASCA Wavefront Analyzer is able to measure the refractive error (sphere) of an eye with a precision of ±0.15 dpt or ±0.50 dpt depending on the range when the distance is absolutely correct aligned. For uncertainties in the distance alignment the displayed sphere value shows an additional deviation from the real ones. This deviation increases with the absolute value of the sphere.

The figure below will help you to classify the results of a certain measurement with respect to the error in sphere you may expect. It shows the error within a measured sphere can deviate from the real sphere value. The colored curves represent the respective errors for a given uncertainty in the distance alignment ranging from 0 mm to 5 mm in one millimeter steps. You will e.g. get an error below ±0.25 diopters for measured sphere values ranging from about –9 D to 5.5 D if you align the measure head within ±1 mm from the best focus (blue curve).



The diagram obviously shows the following fact: the more precise you align the measure head for best focus the smaller the error.

You can use this diagram also to get the error in case of non pure sphere but also cylinder contributions (restricted to max. 3 D cylinder). Simply dismantle sphere/cylinder into sphere/sphere representation (perpendicular axis representation) and use the maximum error you get for the respective sphere values out of the diagram.

Although the refractive values (sphere and cylinder) exhibit a serious dependence on the working distance of the measure head, common amounts of higher order aberrations in human eyes (3rd and 4st order ZERNIKE coefficients < 2 µm) are not very sensitive to a misalignment of the distance. The steep slope of large sphere values leads to a fast deviation of the wavefront traveling towards the analyzer. The mostly flat higher order terms don't change very rapidly.

WASCA Wavefront Analyzer: Operating environment

Temperature:	10–32°C, non-condensing
Humidity:	35–65 % relative humidity
Ambient light:	Measures accurately in ambient room light

Computer, TFT flat screen and Printer

For technical data and further specification details, please refer to the supplier's documentation.

3 Safety instructions

Please read the following safety instructions carefully.

Further important safety information relating to concrete states and situations can be found in each chapter of this User Manual.

3.1 Customer's safety obligations

The Workstations TOSCA TMS-2N, TOSCA TMS-3 and WASCA was designed and produced in accordance with the applicable harmonized norms and further technical specifications. It is a state-of-the-art product and warrants the highest measure of safety.

This level of safety can be maintained in practical use of the system only if all required measures are taken. It is the obligation of the customer of the system to plan and supervise the performance of these measures.

The customer is responsible, in particular to ensure the following:

- to use the system only for the intended purpose;
- to operate the system only in perfect technical state with no function impaired;
- to maintain the User's Manual and all OEM documentation material in good condition and complete and store them on or near the machine;
- to allow only sufficiently qualified and authorized personnel to operate, maintain and repair the machine;
- to ensure regular instruction of such personnel in all matters pertaining to the machine and any of its components and make certain that all operators know the User's Manual and, in particular, the safety instructions;
- to make certain that none of the hazard warning labels on the system is removed or made illegible.

3.2 Requirements on the user

The workstations TOSCA TMS-2N, TOSCA TMS-3 and WASCA must only be used by qualified and instruction ophthalmologists or optometrists.

information on additional requirements, qualifications and competences is contained in all chapters of this Manual.

The user of the workstations should rely on his or her own skill, knowledge, expertise and judgment when making decisions as to operative procedures and should not rely solely on the suggested parameters provided by the software, which is a calculating tool only dependent on data acquired by topography systems.

The user of the workstations must have knowledge of the WIN 98 operating system.

3.3 Product safety

3.3.1 Correct usage

TOSCA Workstation TMS-2N

The topographic system TOSCA Workstation TMS-2N is an advanced system for the acquisition and diagnosis of the superficial conditions of the cornea.

It provides data for the planning, design and later performance of refractive interventions, e.g., correction of decentering, irregularities and asymmetry with the Excimerlaser MEL 70 *G-Scan*.

TOSCA Workstation TMS-3

The topographic system TOSCA Workstation TMS-3 is an advanced system for the acquisition and diagnosis of the superficial conditions of the cornea.

It provides data for the planning, design and later performance of refractive interventions, e.g., correction of decentering, irregularities and asymmetry with the Excimerlaser MEL 70 *G-Scan*.

WASCA Workstation

The topography system WASCA workstation is an up-to-date system for logging and diagnosing the imaging characteristics of the whole eye, sphere, cylinder and especially higher-order imaging defects (Zernike coefficients of the 3^{rd} + 4^{th} order).

It supplies data for the planning, design and later performance of refractive intervention, e.g., correction of imaging defects of the whole eye by customized ablation of the cornea with the Excimerlaser MEL 70 *G-Scan*.

3.3.2 Transport, Setting-up and Start-up

Transport, installation and start-up are carried out by the authorized representative of Asclepion-Meditec.

Together with the installation of the system, the service technician of Asclepion-Meditec carries out a function test as required by MPG and EC directive and instructs the operators in the use of the workstation. The training is recorded and signed in a delivery report.

The workstations are high-precision measuring instruments and must not be exposed to strong vibration.

Please provide sufficient space all around the workstation for easy access to all components.

Use the Workstations in a room with electrical installation satisfying the national requirements (in Germany: VDE 0100).

Install all cables and lines so nobody can trip or cables can be damaged. Live cables or components can cause injury, including death, by electric current.

3.3.3 Electrical safety

Use the Workstations in a room with electrical installation satisfying the national requirements (in Germany: VDE 0100).

Avoid any contact and do not clean the electrical components of the workstations with water or similar fluid.

Work on the electrical equipment of the workstations must only be carried out by a trained electrician.

The use of portable multiple socket outlets with common ground wire is not permitted. Use only the separating transformer supplied with the workstation.

For safety reasons it is forbidden to make any unauthorized modifications to the workstations.

Use only original spare parts / original wearing parts / original accessory items – these parts and items are designed specifically for use with the workstations. Other parts may not be designed and manufactured to conform to the function and safety requirements of original parts.

Parts and special equipment which are not supplied by us must not be used with our workstations.

In case of fire, disconnect the equipment from the power source immediately.

Use only CO_2 fire extinguisher to extinguish fire.

3.3.4 Periodic safety checks

These workstations are subject to regular safety inspection and calibration of all optical components. The results must be recorded in the medical equipment book.
Also see chapter 8.2 "Maintenance".

Inspect the electrical equipment regularly for lose connections, damaged lines and damaged housing.

Inspect the mechanical stability of the workstation regularly.

Inspect the documentation and the safety and warning labels on the workstation regularly for missing items.

4 Transport and setting-up

4.1 Transport

Delivery

The consignment with the Workstation was delivered to our carrier in undamaged condition and complete with all required papers. The carrier delivering the system to your place is responsible for speedy and safe transport and delivery of the consignment to you without damage.

If on inspection of the consignment on receipt you find short delivery or damage in transit, this is the responsibility of the carrier delivering the consignment. If you find damage to the consignment in transit, please observe the following points:

- Insist that carrier make a note of the nature of the defect on the consignment note.
- The carrier should immediately inspect the damage or determine the value of the items in short delivery.
- Inform the competent insurance company of the damage or short delivery without delay. Only the insurance company will pay for the supply of the lost or damaged items in the consignment.
- If you fail to note any damage during a visual inspection of the consignment packages but on unpacking you find that a component of the system has been damaged and provided such damage has been caused in transit, inform the carrier of the facts without delay and insist that an inspection of the system components is made.
- Do not dispose of the original packaging unless all matters have been settled with the carrier and the insurance company.

Transport to another location

If later you want to transfer the Workstation to a new site, observe the following points:

- Make sure that no component can drop to the ground.
- The floor over which the system is transported should be level and have sufficient carrying power for vibration-free transport of the system.

Caution!

The Workstation is a measuring instrument of high precision which must not be exposed to strong vibration.

Non-level ground can damage the Workstation.

4.2 Setting-up

4.2.1 Requirements on the room

The room in which the Workstation is installed and operated should permit electrical supply in accordance to national requirements, have a firm floor with a minimum carrying capacity of 100 kg/m².

Danger! **Use the Workstations in a room with electrical installation satisfying the national requirements (in Germany: VDE 0100).**

4.2.2 Unpacking and installation

The Workstation is unpacked and installed by a service technician of Asclepion-Meditec AG. When the Workstation has been set up, the technician will make a function check as required by MPG and EC directive and instruct the user.

Danger! **Install all cables and lines so nobody can trip or cables can be damaged. Live cables or components can cause injury, including death by electric current.**

Caution! **Provide sufficient space all around the workstation for easy access to all components.**

4.2.3 Check for short delivery

Together with the Asclepion-Meditec service technician, inspect the consignment if all components needed to operate the Workstation have actually been delivered.

5 Start-up

The complete initial start-up of the system is carried out by a service technician of Asclepion-Meditec. Together with the installation of the system the technician carries out a function test as required by MPG and EC directive and instructs the operators in the use of the workstation.

5.1 Connection of all system components

All system components are installed by a service technician of Asclepion-Meditec.

For a complete list of labels of all plug connections and other connections on the system components, refer to chapter 2 "Description of units".

Caution!

Make sure of the proper seating of all plugs.

Install all cables to so that nobody can stumble over them.

Disconnect the power supply to all system components before making or breaking any connection.

5.2 Mains power supply

All system components are installed by a service technician of Asclepion-Meditec.

You need a single-phase 220–230 V AC, 50 Hz power source with a 6.3 amp fuse to supply the system (overall system).

Danger!

Use the Workstations in a room with electrical installation satisfying the national requirements (in Germany: VDE 0100).

Disconnect the power supply to all system components before making or breaking any connection.

Install all cables and lines so nobody can trip or cables can be damaged. Live cables or components can cause injury, including death by electric current.

5.3 Turning the system on/off

It is recommended to turn the Workstation ON/OFF at the isolating transformer.

It is also possible to turn the system components ON or OFF at the mains switch of each components.

For details of the location of the mains power switch on each component, please refer to chapter 2 "Description of units".

Note! **Please turn the Workstation ON or OFF at the isolating transformer.**

5.4 Software installation

The complete software required by the system is already installed on the computer and ready for use when it is delivered.

Caution! **Store the installation CD-ROM as well as the reference/configuration 3½" disk in a safe place. Do not expose the installation disk to strong magnetic fields, heat or cold, direct sunlight, moisture or dust. Any software installation or reinstallation has to be performed by an authorized representative of Asclepion-Meditec AG.**

6 Operation

6.1 Qualification of the operator

The Workstations must only be used by qualified and instructed ophthalmologists.

The operator of the system must have knowledge of the WIN 98 operating system.

Danger!

The program should not be solely relied on for determining pre-operative or post-operative procedures. As there is potential for serious injury including patient discomfort, pain, disorientation, loss of degrees of sight and blindness from improper use, at all times the user of the software should be a trained ophthalmologist familiar with the use and operation of the software and theories behind.

The user of the program should rely on his or her own skill, knowledge, expertise and judgment when making decisions as to operative procedures and should not rely solely on the suggested parameters provided by the software, which is a calculating tool only dependent on data acquired by topography machines.

6.2 System-related software

6.2.1 TMS-2N software

The use of the TMS-2N software is described in the delivered operator manual of the supplier, Tomey Corporation.

6.2.2 TMS-3 software

The use of the TMS-3 software is described in the delivered operator manual of the supplier, Fortune Technologies.

6.2.3 WASCA measure software

The use of the WASCA measure software is described in the delivered user manual of the supplier, Asclepion-Meditec AG.

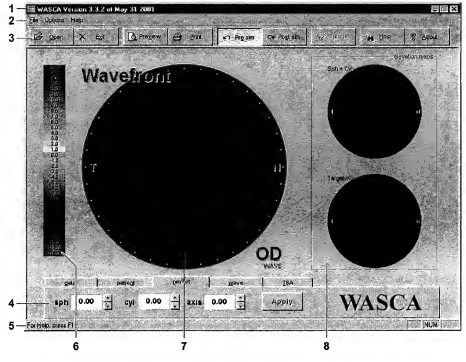
6.3 Ablation Generator Software

6.3.1 Starting the software

To start the software, double-click the software icon.

The main menu of the software is displayed.

6.3.2 The user surface



Legend:

1 Top status line
2 Menu bar
3 Icon bar
4 Register cards
5 Bottom status line
6 Color scale
7 Power map
8 Elevation maps

[1] Top status line

Legend:

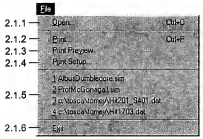
1.1 Software name

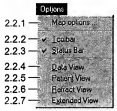
1.2 Minimize window

1.3 Maximize window

1.4 Close the software

[2] Menu bar





Legend:

2.1.1 Opens the window to select a patient data record

2.1.2 Print the current file

2.1.3 Opens the file print preview window

2.1.4 Opens the "Print setup" window of the currently selected printer

2.1.5 Displays the files opened last

2.1.6 Quits the current program

2.2.1 Opens the "Map options" selection window

2.2.2 Hides/shows the icon bar

2.2.3 Hides/shows the bottom status bar

2.2.4 Displays the content of the "data" register card

2.2.5 Displays the content of the "patient" register card

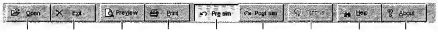
2.2.6 Displays the content of the "refract" register card

2.2.7 Displays the content of the "TSA" register card

2.3.1 Displays help topics for using the software

2.3.2 Displays information on the installation data

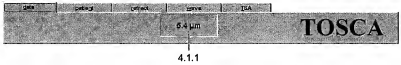
[3] Icon bar



Legend:

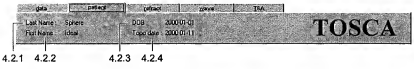
- 3.1 Opens the "Open topofile" window to select a patient data record
- 3.2 Quits the current program
- 3.3 Opens the "Print preview" window
- 3.4 Print the current file
- 3.5 Displays the current file prior to simulation of treatment
- 3.6 Displays the current file after simulation of treatment
- 3.7 Opens the tutorial
- 3.8 Displays help topics for using the software
- 3.9 Displays information on the installation data

[4] Register cards



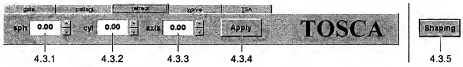
Legend:

- 4.1.1 Displays the value under the mouse pointer



Legend:

- 4.2.1 Displays the patient's family name
- 4.2.2 Displays the patient's first name
- 4.2.3 Displays the patient's date of birth
- 4.2.4 Displays the date of the topographic image exposure



Legend:

4.3.1 Enables the entry of the correction values for the sphere data

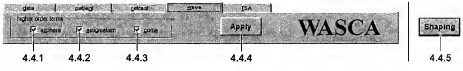
4.3.2 Enables the entry of the correction values for the cylinder data

4.3.3 Enables the entry of the correction values for the axis data

4.3.4 Starts the new calculation with the refraction data. The newly calculated elevation contours is displayed in the "Target" map.

4.3.5 Generates a data record for ablation on the Excimerlaser MEL 70 *G-Scan*. The generated data record is written directly on a CompactFlash-Card.

Note! **Please load a CompactFlash-Card with sufficient free memory space in the USB connection of the computer before starting the <Shaping> function.**



Legend:

4.4.1 Use the correction values for the higher order asphere data

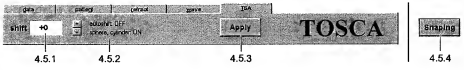
4.4.2 Use the correction values for the higher order astigmatism data

4.4.3 Use the correction values for the higher order coma data

4.4.4 Starts the new calculation with the refraction data. The newly calculated elevation contour is displayed in the "Target" map.

4.4.5 Generates a data record for ablation on the Excimerlaser MEL 70 *G-Scan*. The generated data record is written directly on a CompactFlash-Card.

Note! **Please load a CompactFlash-Card with sufficient free memory space in the USB connection of the computer before starting the <Shaping> function.**



Legend:

4.5.1 Enables entry of the correction values for the shift of the reference area in the Z axis

4.5.2 Status messages

4.5.3 Starts the new calculation with the refraction data. The newly calculated elevation contour is displayed in the "Target" map.

4.5.4 Generates a data record for ablation on the Excimerlaser MEL 70 *G-Scan*. The generated data record is written directly on a CompactFlash-Card.

Note!

The values for Z shifting are entered with the arrow keys beside the input fields.

The values are entered in steps of 1 µm either as incrementing or decrementing value steps.

The maximum value for Z shifting is ± 100 µm.

The refraction data are still enabled in TSA mode even if the value calculated by the software is disabled in TSA mode.

After completing the <Apply> function, a new shift value can be defined by mouseclicking the "Target" map.

Note!

Please load a CompactFlash-Card with sufficient free memory space in the USB connection of the computer before starting the <Shaping> function.

[5] Bottom status line

Legend:

5.1 Displays messages according to the current conditions

5.2 Indicates if the number field of the keyboard is turned on or off

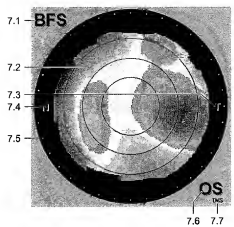
[6] Color scale

Legend:

The color scale displays all colors used, together with their dpt values.

The color scale can change its appearance depending on the source of the invoked patient data record.

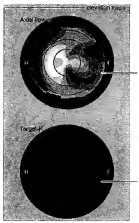
[7] Power map



Legend:

7.1	Best Fit Sphere
7.2	Displays the curvature of the cornea as a color contour, together with the assigned dpt values
7.3	Temporal
7.4	Nasal
7.5	Angle matrix in 10 ° steps
7.6	Displays the eye type
7.7	Displays the machine type

[8] Elevation maps

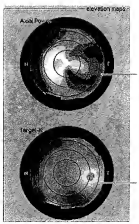


Legend:

8.1a The "Axial Power" map displays the elevation contour of the cornea.

The elevation values are displayed in units of µm.

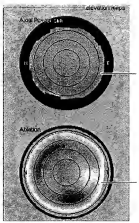
8.2a Before the <Apply> function is performed to obtain an elevation contour of the cornea, the "Target-K" map is blank.



8.1b After using the <Apply> function the current display of the cornea in the "Axial Power" map remains displayed.

8.2b After using the <Apply> function the elevation contour of the "Axial Power" map corrected for the entered refraction data is displayed in the "Target-K" map.

The elevation values are displayed in units of µm.



8.1c After using the <Shaping> function, the result of treating the cornea is displayed in a simulation capture in the "Axial Power sim" map.

8.2c After using the <Shaping> function, the "Target-K" map changes to the "Ablation" map.

The "Ablation" map displays the elevation values of the ablation to be made.

The elevation values are displayed in units of µm.

6.4 Making an examination

6.4.1 Instructing the patient

Explain the patient what is going to happen during the examination
Explain the further procedural steps to the patient.

Caution! **The set-up of the patient place and the handling of the measure head are described in the Operator Manual of the used topographic system.**

6.4.2 Making a topographic image exposure

The topographic image exposure is made and appropriate patient data record generated with the workstation using one of the following software types:

TMS-2N software

The use of the TMS-2N software is described in the delivered operator manual of the supplier, Tomey Corporation.

TMS-3 software

The use of the TMS-3 software is described in the delivered operator manual of the supplier, Fortune Technologies.

WASCA measure software

The use of the WASCA measure software is described in the delivered user manual of the supplier, Asclepion-Meditec AG.

TOSCA

6.4.3 Generating a data record for a TOSCA ablation

The further processing of the topographic data runs under the Ablation Generator Software.

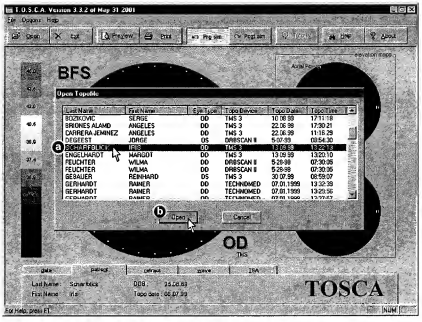
Step 1 **Start the Ablation Generator Software**

To start the software, double-click the software icon.
The main menu of the software is displayed.

Step 2 **Invoke the patient database**

Click <Open> in the icon bar of the main menu.
The patient database is displayed.

Step 3 **Select a patient data record**



Legend:

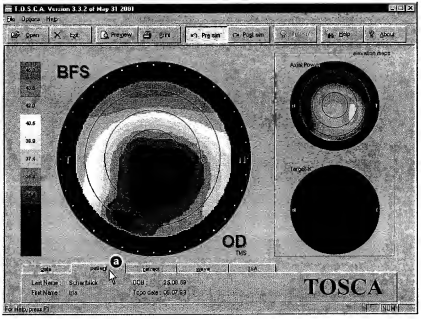
a Click the required data record.
The selected data record is highlighted blue.

b Confirm your selection by clicking <Open>.

Click <Cancel> to exit the selection window without enabling a data record.

TOSCA

Step 4 **Verify the patient data**

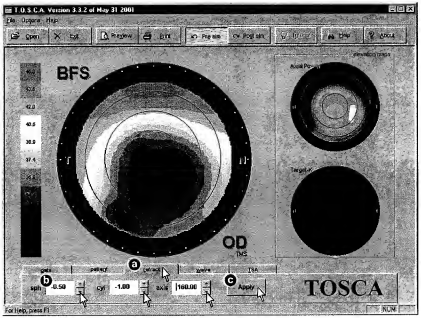


Legend:

a To verify the patient data, click the <patient> register card.

TOSCA

Step 5 **Enter the refraction values**



Legend:

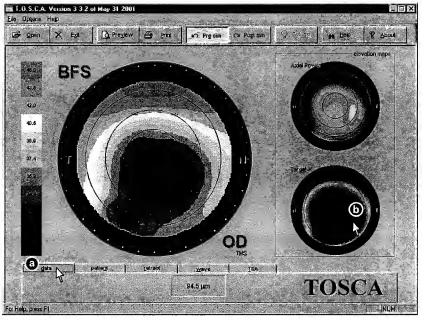
a Open the <refract> register card.

b Enter the patient's current refraction values in the input fields.

c Click the <Apply> button to obtain the display of the new calculation in the "Target" window.

TOSCA

Step 6 **Determine the elevation values in the "Target" window**



Legend:

a Open the <data> register card.

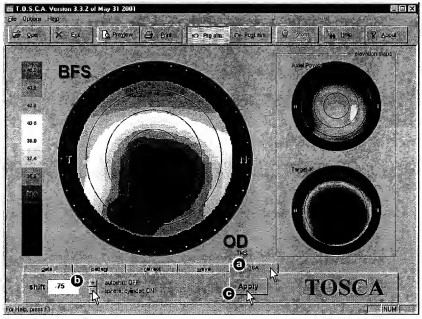
b Place the mouse pointer over the "Target" window.

The current value is displayed in the display window below the mouse pointer.

Determine the highest elevation value along the second ring (counting from the center point).

TOSCA

Step 7 **Set the depth of treatment**



Legend:

a Open the <TSA> register card.

b Enter the value of the shift of the reference area in the Z axis.

c Click the <Apply> button to obtain the display of the new calculation in the "Target" window.

Danger! **If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.**

TOSCA

Step 8 Generate a data record for ablation

Legend:

a Click the <Shaping> button.

A data record for ablation is generated.

The generated data record is written directly on the CompactFlash-Card.

b After using the <Shaping> function, the result of treating the cornea is displayed in a simulation capture in the "Elevation Sim" window.

c The "Ablation" window displays the elevation values of the ablation to be made.

Note!

Load a CompactFlash-Card with sufficient free memory space in the CF-Card-Reader of the computer before starting the <Shaping> function.

TOSCA

Step 9 **Verify the result**

Legend:

a Open the <Data> register card.

b Place the mouse pointer above the "Ablation" window. The current value is displayed in the display window below the mouse pointer.

Adjust the elevation value to the patient data.

c Click the <Pre Sim> button to restore the status before the data record for ablation was generated.

Note! **The lowest point in units of µm should approximately be equal to the refraction (sph + cyl) in units of dpt, multiplied by 13 µm/dpt (plausibility check). If you are in doubt, select a new Z shift value.**

Step 10 **Correct the settings, if necessary**

If you think that the depth should be corrected, open the <TSA> register card once more. Make the required change by entering a different value.

To obtain a new preview, repeat the <Apply> and <Shaping> functions.

Danger! **If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.**

6.4.4 Generating a data record for a WASCA ablation

The further processing of the topographic data runs under the Ablation Generator Software.

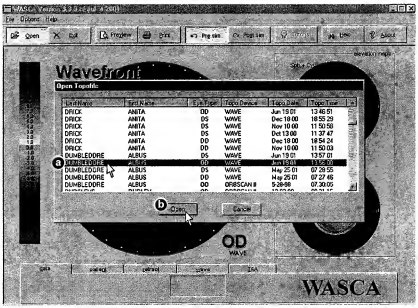
Step 1 **Start the Ablation Generator Software.**

To start the software, double-click the software icon.
The main menu of the software is displayed.

Step 2 **Invoke the patient database**

Click <Open> in the icon bar of the main menu.
The patient database is displayed.

Step 3 **Select a patient data record**



Legend:

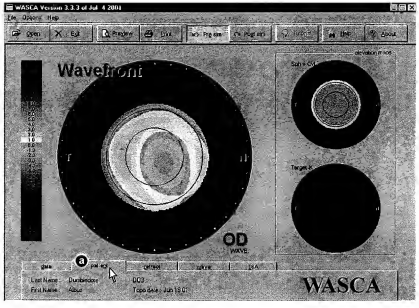
a Click the required data record.
The selected data record is highlighted blue.

b Confirm your selection by clicking <Open>.

Click <Cancel> to exit the selection window without enabling a data record.

W A S C A

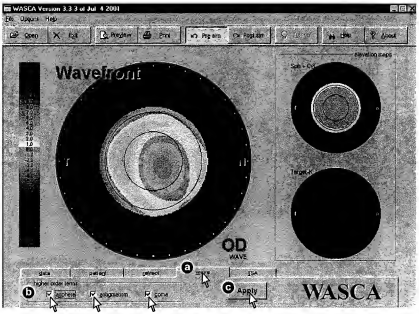
Step 4 **Verify the patient data**



Legend:

a To verify the patient data, click the <patient> register card.

Step 5 Defining the Ablation Program



Legend:

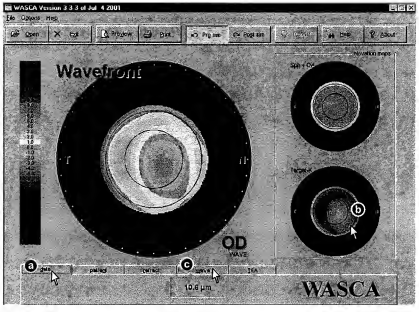
a Open the <wave> register card.

b Select <asphere>, <astigmatism> and <coma>.

c Click the <Apply> button to obtain the display of the new calculation in the "Target" window.

W A S C A

Step 6 **Determine the elevation values in the "Target" window**



Legend:

a Open the <data> register card.

b Place the mouse pointer over the "Target" window.

The current value is displayed in the display window below the mouse pointer.

Determine the highest elevation value. It should be between 5 and 15 µm.

c For creating an ablation file press <Shaping> in the "wave" register card now.

Verify disc with sufficient space is inserted.

⚠ **Danger!** **If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.**

Step 7 **Correct the settings, if necessary**

If you think that the depth should be corrected, open the <TSA> register card once more. Make the required change by entering a different value.

To obtain a new preview, repeat the <Apply> and <Shaping> functions.

⚠ **Danger!** **If you change the depth by a shift of the reference area in the Z axis, you also change the size of the treatment area.**

6.4.5 Printing out the data record overview

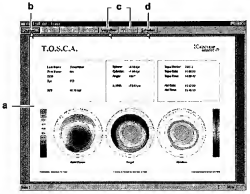
Step 1 **Print Setup**

Click the <Print Setup> button in the <File> menu.
Select the printer that is connected to the system.
Complete the required settings.
To confirm the entries, click <OK>.

Note! **The data screen for the output of the data record overview uses a A4 landscape format as a default.**

Step 2 **Print Preview**

Click the <Preview> button on the icon bar.
The "Print Preview" window is displayed.



Legend:

- **a** It contains an overview of all relevant data.
- **b** A print-out can be obtained from the "Print Preview" window.
- **c** The preview display can be zoomed in or out.
- **d** Closes the "Print Preview" window.

Step 3 **Print**

Click the <Print> button on the icon bar.
The data record overview is printed out.

Note! **The data screen for the output of the data record overview uses a A4 landscape format as a default.**

6.5 Transferring the data record to the Excimerlaser MEL 70 *G-Scan*

Step 1 Remove the CF-Card reader from the computer's USB port.

Step 2 Put the CF-Card reader into the USB port of the Excimerlaser MEL 70 *G-Scan*.

Note! **For Excimerlaser MEL 70 *G-Scan* without USB port a additional ZIP drive must be installed at the workstation. Take the ZIP disk from the Workstation and put it into the ZIP drive installed on the Excimerlaser MEL 70 *G-Scan* (ZIP drive must be connected before starting the MEL 70).**

Step 3 Start the OPASS software unless already started.

Step 4 Select and open the required data record.

Step 5 Again verify the correctness of the selected patient data record.

Danger! **If by chance you should select wrong patient data, serious injury can be caused by the treatment.**

Step 6 Now you can start the treatment in accordance with the operating instructions and the Application Manual of the Excimerlaser MEL 70 *G-Scan*.

Danger! **This User Manual "Workstations" is not an instruction to carry out the treatment on the Excimerlaser MEL 70 *G-Scan* !**

Always refer to the operating instructions and the application manual of the Excimerlaser MEL 70 *G-Scan* !

7 Troubleshooting

If you require the assistance of our customer service department or if you have a question relating to the unit and its handling or the software, please call the Excimer hotline or contact your nearest distributor.

Excimer hotline:

Phone: +49 3641 / 220-444

Facsimile: +49 3641 / 220-442

E-Mail: hotline@asclepion.com

7.1 Hardware problems

Caution!

The Workstations does not contain any parts that can be maintained or repaired by the user.

Only our customer service technicians and other specialists trained by us are authorized to carry out service work on the system.

Any repair attempt by unauthorized personnel can lead to forfeiture of all warranty claims. Besides, functions of the system may be disrupted.

7.2 Fault messages when using the system

The Workstations displays fault messages in non-coded text format.

The message display should help you to remedy any occurring problem.

Note!

This section only deals with fault messages of the Ablation Generator software.

For a remediation of software faults of other programs or of the operating system, refer to the appropriate system manual.

8 Care and maintenance

8.1 Care

Computer table, housings and monitor screens

Clean the computer table and the housings with a soft wet cloth. Remove obstinate dirt with a mild cleaner.

Clean the screen with a soft, dry cloth. Use special screen cleaner if necessary.

Danger! **Do not use a dripping wet cloth. There is risk of electric shock.**

Caution! **Do not use aggressive or abrasive cleaner.**

Optical components

All optical parts are of very high quality. Protect all optical parts from damage and accumulation of dirt.

Caution! **Do not touch any optical surfaces.**
Have customer service personnel clean the optical parts.

8.2 Maintenance

Caution! **These workstations are subject to regular safety inspection and calibration of all optical components. The results must be recorded in the medical equipment book.**

Only Asclepion-Meditec technicians or specialists authorized by Asclepion-Meditec are permitted to carry out cleaning and maintenance of the system!

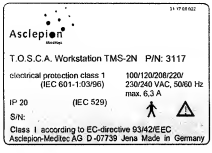
All safety inspections and calibrations of the optical components must be repeated latest after every 12 months.

If you have trouble with the operation of the workstation, please contact our customer service personnel.

9 Further information

9.1 Labeling

TOSCA Workstation TMS-2N

Nameplate	CE-Label	
		

TOSCA Workstation TMS-3

Nameplate	CE-Label	
		

WASCA Workstation

Nameplate	CE-Label	Class 1 laser product
		

9.2 Accessories and replacement parts

Please note that under the Medical Equipment Act you are required to use parts tested and released for use with this system.

For information on certificates confirming the safe use of the system, please refer to chapter 9.5 "Conformity statements".

We urgently advise you not to use accessory components of other suppliers. Asclepion-Meditec cannot accept any liability for any such component.

9.3 Warranty

The Workstation is warranted for a period of 12 months after delivery ex works. The warranty covers all parts manufactured by us and all parts from other manufacturers installed in this system.

We reserve the right to repair defects in the system by replacement of the defective part. The replacement of any part is no reason to claim an extension of the warranty period.

The warranty prescribed by law is available for any part renewed by us.

Defects caused by improper handling of the machine are not covered by our warranty.

9.4 Customer service

If you require customer service or if you have any question regarding the Workstation, please call our Excimer hotline or your distributor.

Excimer hotline

Phone:	+49 36 41 / 220 - 444
Facsimile:	+49 36 41 / 220 - 442
E-Mail:	hotline@asclepion.com

Please note that supplier and distributor will only accept responsibility for the function, reliability and safety of the system if:

- the system was set-up, started, maintained and repaired only by authorized personnel;
- the electrical installation conforms to the legal requirements;
- the system is used in accordance with the instructions.

9.5 Conformity statements

TOSCA Workstation TMS-2N

Asclepion Meditec

Asclepion-Meditec AG, Prüssingstraße 41, 07745 Jena, Germany

Kombination von Produkten mit CE-Kennzeichnung

Combination of CE-compliant products

- TMS-2N
- Software Workstation
- TOSCA

Hiermit erklärt die Asclepion-Meditec AG nach Artikel 12 der EG-Richtlinie 93/42/EWG, daß die nachfolgend angeführten Gerätekombinationen bei bestimmungsgemäßen Einsatz der Einzelkomponenten möglich sind und die gegenseitige Verträglichkeit gemäß den Vorschriften der Hersteller geprüft wurde. Die jeweiligen Gerätekombinationen wurden bei der Asclepion-Meditec AG geprüft und verpackt. Sachdienliche Benutzerhinweise, einschließlich der einschlägigen Hinweise der Hersteller, sind in der Gerätekombination beiliegenden Dokumentation enthalten. Die genannten Tätigkeiten wurden gemäß dem bei der Asclepion-Meditec AG eingeführten Qualitätssicherungssystem durchgeführt und überwacht.
Herewith Asclepion-Meditec AG declares according to Article 12 of Medical Device Directive 93/42/EEC that the following combination of devices are legal if each single component is used in line with it's intended use and the combination is tested and packed by Asclepion-Meditec AG. Relevant information, including all operating manuals of the manufactures are included in the delivered documentation. All these actions were performed and controlled according to the Asclepion-Meditec AG Quality Management System.

Folgende Gerätekombinationen sind möglich / *Legal combinations of devices:*

- TMS-2N (Art.-Nr. 3108) mit TOSCA-Workstation (Art.-Nr. 3117) und Software TOSCA (Art.-Nr. 3104)
TMS-2N (Model-No. 3108) with TOSCA Workstation (Model-No. 3117) and Software TOSCA (Model-No. 3104)

Diese Erklärung ist nur in Verbindung mit den zu den Einzelkomponenten gehörenden EG-Konformitätserklärungen gültig. Bei Änderungen an den Einzelkomponenten oder der Kombination mit nicht aufgeführten Produkten, die nicht von der Asclepion-Meditec AG autorisiert wurden, verliert diese Erklärung ihre Gültigkeit.
This declaration is only valid with the declarations of conformity for each device. Changes of the single devices or combinations with other devices not mentioned without approval by Asclepion-Meditec AG will cause the loss of vollidity of this declaration.

Jena, 27.04.2001

Asclepion-Meditec AG	Asclepion-Meditec AG i.V.
Dr. Michael Dettelbacher	Dr. Dirk Colditz
Vorstand / *CFO*	Qualitätsmanagement / *Quality Management*

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TOSCA Workstation TMS-3

Asclepion

Asclepion-Meditec AG, Prüssingstraße 41, 07745 Jena, Germany

Kombination von Produkten mit CE-Kennzeichnung

Combination of CE-compliant products

- TMS 3
- Software Workstation
- TOSCA

Hiermit erklärt die Asclepion-Meditec AG nach Artikel 12 der EG-Richtlinie 93/42/EWG, daß die nachfolgend angeführten Gerätekombinationen bei bestimmungsgemäßen Einsatz der Einzelkomponenten möglich sind und die gegenseitige Verträglichkeit gemäß den Vorschriften der Hersteller geprüft wurde. Die jeweiligen Gerätekombinationen wurden bei der Asclepion-Meditec AG geprüft und verpackt. Sachdienliche Benutzerhinweise, einschließlich der einschlägigen Hinweise der Hersteller, sind in der Gerätekombination beiliegenden Dokumentation enthalten. Die genannten Tätigkeiten wurden gemäß dem bei der Asclepion-Meditec AG eingerichteten Qualitätssicherungssystem durch geführt und überwacht.
Herewith Asclepion-Meditec AG declares according to Article 12 of Quality Device Directive 93/42/EEC that the following combination of devices are legal if each single component is used in line with it's intended use and the combination is tested and packed by Asclepion-Meditec AG. Relevant information, including all operating manuals of the manufactures are included in the delivered documentation. All these actions were performed and controlled according to the Asclepion-Meditec AG Quality Management System.

Folgende Gerätekombinationen sind möglich / *Legal combinations of devices*:

- TMS 3 (Art.-Nr. 4640) mit TOSCA Workstation (Art.-Nr. 3107) und Software TOSCA (Art.-Nr. 3104)
  TMS 3 (Model-No. 4640) with TOSCA Workstation (Model-No. 3107) and Software TOSCA (Model-No. 3104)

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Jena, 17.02.2000

Asclepion-Meditec AG
Dr. Michael Dottelbücher
Vorstand / *Director*

Asclepion-Meditec AG
i.V.
Dr. Dirk Colditz
Qualitätsmanagement / *Quality Management*

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WASCA Workstation

Asclepion Meditec

Asclepion-Meditec AG, Prüssingstraße 41, 07745 Jena. Germany

Kombination von Produkten mit CE-Kennzeichnung

Combination of CE-compliant products

- WASCA Wavefront Analyzer mit WASCA Measure Software
- WASCA-Workstation
- TOSCA Ablation Generator

Hiermit erklärt die Asclepion-Meditec AG nach Artikel 12 der EG-Richtlinie 93/42/EWG, dass die nachfolgend angeführten Gerätekombinationen bei bestimmungsgemäßem Einsatz der Einzelkomponenten möglich sind und die gegenseitige Vereinbarkeit gemäß den Vorschriften der Hersteller geprüft wurde. Die jeweiligen Gerätekombinationen wurden bei der Asclepion-Meditec AG geprüft und verpackt. Sachdienliche Benutzerhinweise, einschließlich der einschlägigen Hinweise der Hersteller, sind in der Gerätekombination beiliegenden Dokumentation enthalten. Die genannten Tätigkeiten wurden gemäß dem bei der Asclepion-Meditec AG eingerichteten Qualitätssicherungssystem durchgeführt und überwacht.
Herewith Asclepion-Meditec AG declares according to Article 12 of Medical Device Directive 93/42/EEC that the following combination of devices are legal if each single component is used in line with it's intended use and the combination is tested and packed by Asclepion-Meditec AG. Relevant information, including all operating manuals of the manufactures are included in the delivered documentation. All these actions were performed and controlled according to the Asclepion-Meditec AG Quality Management System.

Folgende Gerätekombinationen sind möglich / *Legal combinations of devices*:

- WASCA Wavefront Analyzer (Art.-Nr. 3111) mit WASCA-Workstation (Art.-Nr. 3112) und Software TOSCA Ablation Generator (Art.-Nr. 3106)
  WASCA Wavefront Analyzer *(Model-No. 3111) with WASCA Workstation (Model-No. 3112)* and Software TOSCA Ablation Generator (Model-No. 3106)

Diese Erklärung ist nur in Verbindung mit den zu den Einzelkomponenten gehörenden EG-Konformitätserklärungen gültig. Bei Änderungen an den Einzelkomponenten oder der Kombination mit nicht aufgeführten Produkten, die nicht von der Asclepion-Meditec AG autorisiert wurden, verliert diese Erklärung ihre Giltigkeit.
This declaration is only valid with the declarations of conformity for each device. Changes of the single devices or combinations with other devices not mentioned without approval by Asclepion-Meditec AG will cause the loss of validity of this declaration.

Jena, 03.05.2001

Asclepion-Meditec AG	Asclepion-Meditec AG i.V.
Dr. Michael Dettelbacher	Dr. Dirk Colditz
Vorstand / CFO	*Qualitätsmanagement / Quality Management*

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Notes:

Appendix C

WASCA Booklet

CARL ZEISS MEDITEC

WASCA Booklet

MEL 70 *G-Scan*

Version 3.0
Closing date 08/2002
Article No. 311199008
WASCA Measure Software V 1.26.3
Ablation Generator Software 3.3.4 and 3.3.5
OPASS Software to 3.1

Carl Zeiss Meditec AG
Göschwitzer Str. 51-52 — 07745 Jena — Germany

EXCIMER HOTLINE
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Facsimile: +49 (0) 36 41/2 20 4 42
E-Mail: hotline@asclepion.com

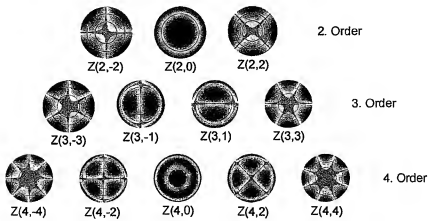
The task of this booklet is to be a short treatment guide for the use of the WASCA-Workstation for wavefront guided treatment with the MEL 70 G-Scan.

1 Basics

To evaluate the quality of an optical system in today's high-tech world we use a wavefront analyzer. By measuring a wavefront having passed through an optical system and thus being distorted we can evaluate the performance. One can describe these distortions with the aid of the so-called Zernike polynomials.

For a better understanding you can see a graphic display of the most important Zernike polynomials below.

Zernike Polynomials



Whereas the second order terms describe the well known parameters of sphere and cylinder, the third and fourth order terms represent the so called high order aberrations.

The aberration table of the WASCA Workstation is displaying not only sphere, cylinder, axis, pupil diameter, analysis diameter and the Zernike coefficients, but also the PV OPD (peak-to-valley optical path difference) and the RMS OPD (root mean square value of OPD). The values PV OPD and RMS OPD refer to the whole wavefront. The values PV OPD HO and RMS OPD HO, however, refer only to the 3rd and 4th order. These values are displayed in µm and describe the wave front.

Note! These values should not be considered like elevation maps of a topography machine.

2 Measurement conditions

After the patient is set and the machine is roughly aligned, the pupil diameter of the patient is increased to a maximum by dimming the room light and target light (not by a mydriaticum that might change the aberrations).

The patient should fixate on the center of the internal fixation target.

It has to be assured that the pupil is at least 5 mm wide (refer to 5.1 for details).

3 Patient Selection

Up to now we have no experience in treating high order aberrations of hyperopic patients.

Zernike coefficients of less than 0.2 µm cannot seriously be interpreted with respect to clinical relevance.

For treatment you should use patients who have a ablation depth higher than at least 5 µm. Values above 15 µm should also not be treated since too great ablation differences could have an influence of the refractive outcome (refer to 5.4 for details).

4 General description of the procedure

The aberrometric treatment is done in two steps. At first sphere and cylinder are treated as usual.

Make sure that the subjective refraction value of the patient is corrected according to his high order aberrations (refer to 5.2 and 5.6 for details).

In a second step the higher order aberrations are treated using the WASCA ablation file coming from the WASCA workstation (refer to 5.1 for details).

Make sure that the MEL 70 centration is done referring to center of the entrance pupil while the patient is fixating the target light for the high order correction. This is necessary since the wavefront measurement and Zernike expansion use the pupil center as a reference.

5 WASCA - Checklist

5.1 How to perform a WASCA measurement

- Perform the WASCA measurement in dark room conditions to determine the patients wavefront error for his mesopic pupil size
- Open "Database" "Add Patient" and fill in the form or select the patient if it is already in the list.
- Click on "Start" and adjust the aberrometer according to the users manual.
- The patient should fixate on the center of the internal fixation target.
- Click on "Refract" and "Capture Measurement".
- Set the "Analysis Diameter" preset ① to a value higher than the actual pupil size "Pupil Diameter" ③. This ensures that all data is used for the calculation of the ablation file. However, a pupil size above 7mm might be a contraindication for the intended refractive treatment.
- Make sure that "Pupil Diameter" ③ is at least 5mm.
- Make sure that "Sphere" ②correlates with the patients manifest refraction.
- Note the parameters "Pupil Diameter" ③ and Z(4,0) ④.
- Finally click on "Write to Database".

① Analysis Diameter: 7

	quantity		value
②	**sphere**	X	**-3.02 d**
	cylinder	X	**-0.48 d**
	axis		129°
③	pupil diameter		6.75 mm
	analysis diameter		6.75 mm
	PV OPD		20.12 µm
	RMS OPD		5.20 µm
	PV OPD HO		2.59 µm
	RMS OPD HO		0.55 µm
	Z(3,-3)		0.236 µm
	Z(3,-1)		-0.590 µm
	Z(3,1)		0.753 µm
	Z(3,3)		-0.045 µm
	Z(4,-4)		0.075 µm
	Z(4,-2)		-0.149 µm
④	Z(4,0)		-0.908 µm
	Z(4,2)		-0.079 µm
	Z(4,4)		-0.158 µm
	x offset		0.22 mm
	y offset		0.13 mm

Fig 1: WASCA aberration table

5.2 How to correct the subjective refraction for the MEL 70

The WASCA treatment of higher order aberrations influences the refractive result. Depending on the spherical aberration of the patient and the intended treatment diameter (which must match the WASCA analysis diameter), you should correct the subjective refraction according to the following table.

- Choose the "$\varnothing_{Analysis}$" column and the "Z(4,0)" row which comes closest to the patient values. Read the correction out of the table below (Fig 2),
- Add this correction value to the patients subjective refraction before typing it into the MEL 70.
- For the patient from 5.1 : Pupil Diameter = 6,75mm

  Z(4,0) = -0,908µm

  Subjective Refraction = -2,0 D

  -2,0D + (-0,5D) = **-2,5D**
- The corrected value of –2,5D has to be used for the treatment of sphere and cylinder described in section 5.6.

Z(4,0)							
-1,50 µm	1,50	1,25	1,00	0,75	0,75	0,75	0,50
-1,40 µm	1,25	1,00	1,00	0,75	0,75	0,50	0,50
-1,30 µm	1,25	1,00	0,75	0,75	0,75	0,50	0,50
-1,20 µm	1,25	1,00	0,75	0,75	0,50	0,50	0,50
-1,10 µm	1,00	0,75	0,75	0,50	0,50	0,50	0,50
-1,00 µm	1,00	0,75	0,75	0,50	0,50	0,50	0,50
-0,90 µm	0,75	0,75	0,50	0,50	0,50	0,50	0,25
-0,80 µm	0,75	0,75	0,50	0,50	0,50	0,25	0,25
-0,70 µm	0,75	0,50	0,50	0,50	0,25	0,25	0,25
-0,60 µm	0,50	0,50	0,50	0,25	0,25	0,25	0,25
-0,50 µm	0,50	0,50	0,25	0,25	0,25	0,25	0,25
-0,40 µm	0,50	0,25	0,25	0,25	0,25	0,25	0,25
-0,30 µm	0,25	0,25	0,25	0,25	0,25	0,25	
-0,20 µm	0,25	0,25	0,25				
$\varnothing_{Analysis}$	**5,0 mm**	**5,5 mm**	**6,0 mm**	**6,5 mm**	**7,0 mm**	**7,5 mm**	**8,0 mm**
-0,20 µm	-0,25	-0,25	-0,25				
-0,30 µm	-0,25	-0,25	-0,25	-0,25	-0,25	-0,25	
-0,40 µm	-0,50	-0,25	-0,25	-0,25	-0,25	-0,25	-0,25
-0,50 µm	-0,50	-0,50	-0,25	-0,25	-0,25	-0,25	-0,25
-0,60 µm	-0,50	-0,50	-0,50	-0,25	-0,25	-0,25	-0,25
-0,70 µm	-0,75	-0,50	-0,50	-0,50	-0,25	-0,25	-0,25
-0,80 µm	-0,75	-0,75	-0,50	-0,50	-0,50	-0,25	-0,25
-0,90 µm	-0,75	-0,75	-0,50	-0,50	-0,50	-0,50	-0,25
-1,00 µm	-1,00	-0,75	-0,75	-0,50	-0,50	-0,50	-0,50
-1,10 µm	-1,00	-0,75	-0,75	-0,50	-0,50	-0,50	-0,50
-1,20 µm	-1,25	-1,00	-0,75	-0,75	-0,50	-0,50	-0,50
-1,30 µm	-1,25	-1,00	-0,75	-0,75	-0,75	-0,50	-0,50
-1,40 µm	-1,25	-1,00	-1,00	-0,75	-0,75	-0,50	-0,50
-1,50 µm	-1,50	-1,25	-1,00	-0,75	-0,75	-0,75	-0,50

Fig 2: Subjective refraction correction table

5.3 How to load the wavefront data into the WASCA Ablation Generator

- Double-click the WASCA Ablation Generator on the Windows desktop or switch to the program by pressing "Alt-Tab".
- Press the "OPEN"-button and select the patient out of the list (Fig. 3)

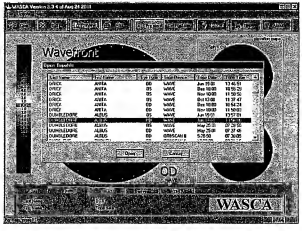


Fig 3: Patient selection menu

- Check OS/OD, device and the date of the measurement, then press "Open" to load the patient data.

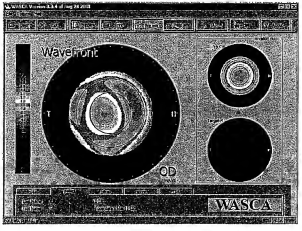


Fig 4: Patient data and wavefront maps

- Check again the patient name, OS/OD, device and the date of the measurement.
- Check the data diameter (the circular rings in the map show a 3mm, 5mm and 7mm zones). The zone with wavefront data should match approx. the pupil diameter of the measurement (approx. 6mm in Fig 4).
- The main map shows a colour map of the higher order wavefront error, the top right shows a colour map of the spherocylindrical component of the wavefront.

5.4 How to check the ablation depth

- Open "wave" and select asphere, astigmatism and coma (default).
- Press "apply" to generate the ablation map (Fig 5, bottom right map).

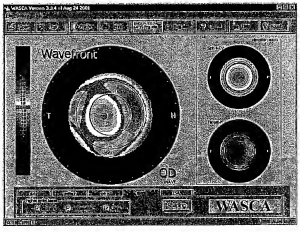


Fig 5: Wavefront maps and ablation map

- Click the right mouse button in the main map and select "Target Map". This generates the ablation map in the main map. It's easier now to determine the location of the maximum ablation depth.

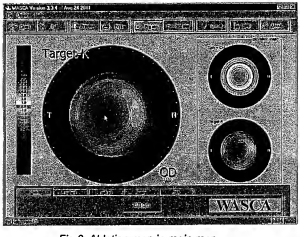


Fig 6: Ablation map in main map

- Determine the position of the deepest ablation. The local ablation depth is shown for each point under the mouse pointer (Fig 6).
- The maximum ablation depth should be between 5µm and 15µm.

5.5 How to create the ablation file

Note! Don't type in the patients refraction, the WASCA ablation generator doesn't perform a correction of sphere and cylinder. Don't use the TSA functions to create or modify the ablation file !

- Open "wave" and press "apply" again.
- Put the Compact-Flashcard-Reader into the USB-port at the WASCA-PC. For stations with ZIP-drive: A ZIP-disk must be in the ZIP-drive.
- For creating the ablation file press "shaping" now.
- Now the main map shows the real ablation file incl. the transition zone (Fig 7).

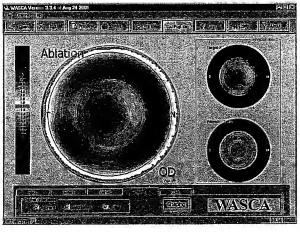


Fig 7: Map of the real ablation file in main map

5.6 Step 1 : Treatment of sphere & cylinder

- Perform the correction of sphere and cylinder as usual.
- Check that you have corrected the subjective refraction as described in 5.2. before typing it into the OPASS.

5.7 Step 2 : Treatment of the high order aberrations

- Take the Compact-Flashcard-Reader from the WASCA station (USB-port WASCA-PC) and put it into the USB-port at the MEL70.
- For MEL70 without USB-connector an additional ZIP-drive must be installed at the workstation. Take the ZIP-disk from the WASCA station and put it into the ZIP-drive installed on the MEL70 (ZIP-drive must be connected before starting the MEL70)
- Press the "topographical treatment" button and select the patient out of the list.
- Skip the fluence test and press "ready".
- Switch on the eye tracker and center the target beam. Make sure that the centration is done referring to center of the entrance pupil !
- Perform the WASCA treatment.

Notes